

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Microchips, Inc. (WO 02/30401). Microchips discloses a medical device (Fig. 2) for controlled release of one or more substances (abstract) into a body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig. 2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface, they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of the blister-like vesicles are electrodes and

both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22).

In reference to claims 2-4 see page 8, line 34 and Fig. 2.

In reference to claim 5, page 7, lines 1-5 disclose that the device may be implanted in vivo in gastrointestinal fluids or urine, which would indicate that the device would be placed in either a digestive tract organ or the urinary bladder.

In reference to claim 6, see page 5, line 29 through page 6, line 1 as well as page 6, lines 24-25.

In reference to claims 12-14, see page 3, lines 33-34.

In reference to claims 15 and 16, see page 8, line 15 through page 9, line 5.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses the device substantially as claimed including that the device is used in bodily fluids such as urine to treat the bladder (page 7, lines 1-5), Microchips, however, does not disclose an inflatable balloon with magnetic portion and valve. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46-48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64-65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips with the delivery device as taught by Yachia, as the device of Microchips is

used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

Claims 17 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses a system for treating a body cavity of an individual, the system comprising: a medical device (Fig. 2) for controlled release of one or more substances (abstract) into a body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig. 2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface, they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of the blister-like vesicles are electrodes and both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the

first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22).

Microchips, however, does not disclose an inflatable balloon with magnetic portion and valve. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46-48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64-65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Yachia also discloses an inflating device for inflating the balloon (Fig. 4a, 7). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips with the delivery device as taught by Yachia, as the device of Microchips is used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device

including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

In reference to claim 19, Yachia discloses a magnetic displacing member (Fig. 13, 51 and 52) for displacing the device within the body cavity. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the magnetic displacing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 4, lines 62-65).

In reference to claims 20 and 21, Yachia discloses an immobilizing member (Fig. 14, 75) comprising a magnetic portion (72), said immobilizing member being secured onto the individual's body for immobilizing the device at a desired location in the body cavity (Fig. 14). Yachia further discloses that the immobilizing member is a hygienic pad configured to be placed in a garment of the individual (col. 7, lines 39-41). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the magnetic immobilizing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 5, lines 2-3).

In reference to claims 22-24, Yachia, however, discloses that the gripping device has flanges (Fig. 5a, 23), is magnetic (Fig. 11, 29) and the inflating device comprises an injector (Figs. 4a and 4b, 7). Therefore it would have been obvious to one of ordinary

skill in the art at the time of the invention to have modified Microchips with the magnetic gripping member and inflating member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 6, lines 56-61).

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses a method for releasing one or more substances into a body cavity containing an electrolytic fluid of an individual, the system comprising: loading the one or more substances into the vesicles of a medical device (Fig. 2) for controlled release of one or more substances (abstract) into a body cavity as well as inserting the device into the body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig. 2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface, they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of

the blister-like vesicles are electrodes and both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22).

Microchips, however, does not disclose an inflatable balloon with magnetic portion and valve, nor expanding the balloon in the body cavity or displacing the balloon within the urinary bladder to a desired location. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46-48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64-65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Yachia also discloses an inflating device for inflating the balloon (Fig. 4a, 7). Yachia, however, discloses expanding a balloon in a urinary bladder (Fig. 9)



and displacing the balloon within the bladder to a desired location (Fig. 13). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips with the delivery device as taught by Yachia, as the device of Microchips is used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

In reference to claim 27 see Figs. 9 and 13 of Yachia.

In reference to claim 28, see page 3, lines 33-34 of Microchips.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 2/19/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application 10/533640 and US Patent Nos. 6398718, 6293923, 6746421 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

Applicant's arguments, see pages 10 and 11, filed 2/19/2008, with respect to the rejection(s) of claim(s) 1-28 under double patenting rejections and 112 rejections have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Art Unit: 3767

However, upon further consideration, a new ground(s) of rejection is made in view of Microchips, Inc. Upon reviewing the application file and the claims in order to place the application in condition for allowance, the examiner believes that the Microchips reference can be used to reject the claims as they are currently worded.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767